

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT
TRANSLATION

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

| | | | |
|---|---|---|-------------------------------------|
| | | | Date of mailing (day/month/year) |
| Applicant's or agent's file reference P04-159 | | FOR FURTHER ACTION See paragraph 2 below | |
| International application No. PCT/JP2005/000064 | International filing date (day/month/year) 06.01.2005 | Priority date (day/month/year) 14.01.2004 | |
| International Patent Classification (IPC) or both national classification and IPC | | | |
| Applicant OTSUKA PHARMACEUTICAL FACTORY, INC. | | | |

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | |
|--|--------------------|
| Name and mailing address of the ISA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000064

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 in written format
 in computer readable form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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| International application No. | PCT/JP2005/000064 |
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| Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
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1. Statement

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|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-11</u> | YES |
| | Claims _____ | NO |
| Inventive step (IS) | Claims <u>1-11</u> | YES |
| | Claims _____ | NO |
| Industrial applicability (IA) | Claims <u>1-11</u> | YES |
| | Claims _____ | NO |

2. Citations and explanations:

Document 1: WO 02/074200 A1 (CYDEX, INC.) 26 September 2002

Document 2: JP 6-128149 A (Japan Tobacco Inc.) 10 May 1994

Document 3: WO 96/32135 A1 (FARMARC NEDERLAND BV OF CITCO TRUST INTERNATIONAL MANAGEMENT) 17 October 1996

<Claims 1-11>

The inventions of claims 1-11 are not disclosed in any of the documents cited in the ISR and they do not appear to be novel or to involve an inventive step.

In particular, propofol-containing fat emulsion preparations capable of alleviating angialgia at a time of intravenous administration or intravenous drip injection administration that contain 0.1 to 5 w/v% of propofol, 2 to 20 w/v% of oil component, 0.4 to 10 w/v% of emulsifier and 0.02 to 1 w/v% of cyclodextrin are not disclosed in any of documents 1-3, which are found to be the most relevant prior art documents.

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| International application No. |
| PCT/JP2005/000064 |

| Box No. VI | Certain documents cited | | | | | | | | |
|--|--|---|--|---|---|---|------------|------------|--|
| <p>1. Certain published documents (Rule 43bis.1 and 70.10)</p> <table border="1"> <thead> <tr> <th align="left">Application No. Patent No.</th> <th align="left">Publication date (day/month/year)</th> <th align="left">Filing date (day/month/year)</th> <th align="left">Priority date (valid claim) (day/month/year)</th> </tr> </thead> <tbody> <tr> <td align="left">JP 2005-22989 A <small>(Otsuka Pharmaceutical Factory, Inc.)</small> [E, X]</td> <td align="left">27.01.2005</td> <td align="left">30.06.2003</td> <td></td> </tr> </tbody> </table> | | Application No. Patent No. | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) | JP 2005-22989 A <small>(Otsuka Pharmaceutical Factory, Inc.)</small> [E, X] | 27.01.2005 | 30.06.2003 | |
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| JP 2005-22989 A <small>(Otsuka Pharmaceutical Factory, Inc.)</small> [E, X] | 27.01.2005 | 30.06.2003 | | | | | | | |
| <p>2. Non-written disclosures (Rule 43bis.1 and 70.9)</p> <table border="1"> <thead> <tr> <th align="left">Kind of non-written disclosure</th> <th align="left">Date of non-written disclosure (day/month/year)</th> <th align="left">Date of written disclosure referring to non-written disclosure (day/month/year)</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table> | | Kind of non-written disclosure | Date of non-written disclosure (day/month/year) | Date of written disclosure referring to non-written disclosure (day/month/year) | | | | | |
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